

FEB 08 2002

ATTACHMENT 6 - 510(k) Summary**1. Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)

Reservoir Place

1601 Trapelo Road

Waltham, MA 02451

Telephone Number: 781-890-0001

Fax Number: 781-890-6464

Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. Name of the Device

Trade Name: ITI Esthetic Ease Abutments

Common Name: Dental implant abutment

Classification Name: Endosseous dental implants
21 CFR 872.3640

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

ITI synOcta Abutment (K990342)

ITI Wide Neck Implant synOcta Abutment (K013798)

4. Description of the Device

The ITI Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments, and surgical and prosthetic parts and instruments. The devices covered by this submission are abutments which are placed into the dental implant to provide support for a prosthetic reconstruction. The subject abutments are indicated for cemented restorations, particularly in esthetic areas of the mouth.

The ITI esthetic abutments are made from commercially pure Grade 4 titanium (ASTM F67) with a titanium alloy screw. The basal portion of the abutment has conical taper with an inset octagonal design. The abutment is placed over the implant shoulder and is mounted into the implant with a

screw. The abutment is available in two diameters for use with ITI implants with shoulder diameters of 4.8 mm and 6.5 mm.

5. **Intended Use of the Device**

The devices covered by this submission are abutments which are placed into the dental implant to provide support for a prosthetic reconstruction. The subject abutments are indicated for cemented restorations, particularly in esthetic areas of the mouth. The abutment can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

6. **Basis for Substantial Equivalence**

The ITI esthetic abutments are substantially equivalent in intended use, material, and design to the ITI synOcta abutments cleared under K990342 and ITI Wide Neck Implant synOcta abutments cleared under K013798.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 08 2002

Institut Straumann AG
C/O Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
1601 Trapelo Place
Waltham, Massachusetts 02451

Re: K020096
Trade/Device Name: ITI Esthetic Abutments
Regulation Number: 872.3640
Regulation Name: Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: January 9, 2002
Received: January 11, 2002

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

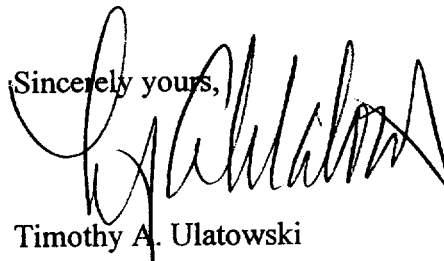
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020096

Device Name: ITI Esthetic Abutments

Indications For Use:

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The ITI Esthetic abutments are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

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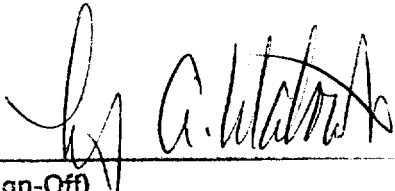
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020096